

## **REMARKS**

Reconsideration of the claims of the instant application is respectfully requested in view of the above amendments and the following remarks. Claim 26 is amended. Claims 21, 23, and 24 have been withdrawn without prejudice.

The Examiner issued a Restriction Requirement where he requested that the Applicants elect a species of diseases recited in the claims. Applicants elect hemochromatosis with traverse. Claims 1, 3, 4, 15, 16, 22, 25, and 26 read on the elected species. Claims 27-30 are drawn to a method of detecting hepcidin and do not recite any diseases. No requirement to withdraw claims 27-30 had been presented in the instant Restriction Requirement. Accordingly, Applicants respectfully request the Examiner to examine claims 27-30 on merits in addition to claims 1, 3, 4, 15, 16, 22, 25, and 26.

As discussed in the response to the previous Office Action, the meaning of term “indicative” as used in claim 1 is consistent with Steadman’s Medical Dictionary, 22<sup>nd</sup> Ed. which defines “indication” as “suggestion or pointer.” Accordingly, the detection of the abnormal hepcidin level does not need to conclusively prove that the patient has certain disease or condition, but rather may serve as an additional criterion for diagnostics of that disease. It is a normal diagnostic practice that the results of several different tests are taken together to conclusively prove whether a patient has the disease in question. Accordingly, if it is known that certain disease or condition is characterized by abnormal hepcidin levels, a person of ordinary skill in the art (and in this case, the ordinary skill in the art is, unquestionably, high) would consider the abnormal hepcidin level in diagnosing a disease.

The instant invention discloses methods of detecting and quantifying hepcidin in human samples. The claimed methods allow for detection of hepcidin which is above the normal range, within the normal range, or below the normal range of hepcidin. Since the Examiner has noted that the diagnosis of hereditary hemochromatosis is enabled, it follows that a detection of a decreased amount of hepcidin, compared to the normal range, is also inherently enabled. By the same logic, the Examiner has noted that the diagnosis of chronic renal insufficiency is enabled. Therefore, detection of increased amount of hepcidin is also inherently enabled.

Applicants respectfully submit that without the requested election, no undue burden would be imposed upon the Examiner. The claims of the instant application disclose antibodies which specifically bind to one or more carboxy terminal epitopes of SEQ ID NO: 2. Evidence

on the record shows failure of others in making the antibodies of the instant invention. See, e.g., *Park*, submitted to the attention of the USPTO previously and considered by the Examiner on January 25, 2008.

The closest reference which discloses antibodies to C-terminus of hepcidin, namely *Nemeth*, is not a proper prior art reference in view of the Affidavit of prior inventorship submitted on December 12, 2007, and respectfully request the Examiner to consider it. *Nemeth* has also been considered by the Examiner on January 25, 2008.

Applicants further respectfully note that the record shows that the Examiner extensively researched multiple databases and did not find any references disclosing prepared antibodies which fall within the description of the instantly claimed antibodies. The novelty and non-obviousness of the instant claims is underscored by the fact that no rejections based on § 102 or § 103 have been issued in the Office Action of January 25, 2008. Thus, if claims having fewer limitations are novel and not obvious in view of the prior art, it naturally follows that the claims having more limitations would also be novel and non-obvious. Accordingly, Applicants respectfully submit that the Examiner does not need to do additional research related to novelty and/or obviousness of the instant claims.

Applicants further respectfully note that claim 1 is a linking claim, as all diseases recited in claims 21-26 fall within the groups recited in claim 1. Accordingly, if the Examiner finds that the diseases recited in claim 1 are enabled, Applicants respectfully request a rejoinder of claims 21, 23, and 24.

**CONCLUSION**

In view of these amendments and remarks, applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, Applicants welcome the Examiner to call the undersigned at 609-844-3021.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,

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